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Patents Form 1/77

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Request for grant of a patent

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Gwent NP9 1RH

1	Your reference	SPG/P36067
2	Patent application number	**9904232.7** 25 FEB 1999
3	Full name, address and postcode of the applicant Patents ADP number State of incorporation	JNA Limited Whitland Abbey Whitland Carmarthenshire SA34 OLG 5878186001 England and Wales
4	Title of the invention	Optical Device
5	Name of agent Address for service Patents ADP number	Harrison Goddard Foote Belmont House 20 Wood Lane Headingley Leeds LS6 2AE 1457001

6	Priority applications	Country	Priority App No	Date of Filing

7	Parent application (eg Divisional)	Earlier Application No	Date of Filing
8	Statement of Inventorship Needed?	Yes	
9	Number of sheets for any of the following (not counting copies of same document)		
	Continuation sheets of this form		
	Description	8	
	Claims	1	
	Abstract		
	Drawings	7	
10	Number of other documents attached		
	Priority documents		
	Translations of priority documents		
	P7/77		
	P9/77		
	P10/77		
	Other documents		
11	I/We request the grant of a patent on the basis of this application.		
	Signature S.P. Gilholm	Date 24 Feb 1999	
12	Name and daytime telephone number of person to contact in the United Kingdom	Steve Gilholm	
		+44 113 2258350	

OPTICAL DEVICE

This invention relates to an optical device for monitoring or measuring the arterial oxygen saturation with motion artefact suppression.

Monitors are available which use non-invasive optical techniques to measure the arterial oxygen saturation in patients. As is well known in the art, these instruments suffer interference due to patient movement, motion artefact.

For example, it is known, that in order to measure blood oxygen saturation, it is necessary to provide a device which passes light through biological tissue, such as the human finger, and to monitor the transmitted or reflected output signal from a photodetector of this device continuously. Such devices are described, inter alia, in International Patent Application No WO94/03102. Movement of the subject leads to a change in the length of the path of the light through the biological tissue and hence to a variation in the intensity of light received by the photodetector. This renders the device incapable of distinguishing between changes in received light intensity caused by variations in light absorption by the component being monitored (eg oxygen in the blood), and changes in received light intensity caused by variations in the light pathlength due to movement of the subject.

The problem is common to all optical monitoring devices and can render these devices inoperative for long periods of time. The problem is particularly severe in critical health care applications, were continuous monitoring is essential.

We have now devised an optical measuring or monitoring device which is able to monitor or measure the arterial blood oxygen saturation non-invasively and to suppress the effects of motion artefact.

Melanin is present in increasing concentrations from fair through brown to black skin. The peak of its absorption spectrum is at 500nm decreasing almost linearly

with increasing wavelength. Melanin is present in the epidermis, thus, in very high concentrations as is the case in black skin, it can mask the absorption of haemoglobin in the dermis. Even in brown skin, the absorption by melanin is superimposed on that of haemoglobin so that any algorithm which uses the shape of the absorption spectrum in order to produce SO_2 value needs to compensate for this fact.

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In accordance with this invention, there is provided a sensor device which comprises light source means for emitting a light beam, optionally of a plurality of at least three different wavelengths, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged to provide signals corresponding to the intensities of the respective wavelengths received by the photodetector means the arrangement being such that the signal levels corresponding to the different wavelengths bear a predetermined relationship with each other, and signal processing means for processing the actual output signals from the photodetectors to cancel out variations due to motion artefact and to provide an output representing a parameter to be measured or monitored and substantially unaffected by motion artefact.

The sensor of the invention may use a spectral wavelength of from 526 to 586 nm.

A particular advantage of the sensor of the invention is that it only enables a user to compare "slopes" on a graph and the use of a range of different wavelengths allows

for a more accurate determination without an increase in costs. In a preferred embodiment of the invention 3 or more different wavelengths are used, the optimum number of wavelengths is 5 or 6.

The sensor device of the invention is generally an optical measuring or monitoring device.

The sensor may be attached to the chest or abdomen of an infant. The tip of the sensor may incorporate a mirror and is provided with an optical fibre light transmitting cable such that the fibre cable lies flat on the surface of the skin. White light (20 to 50W quartz halogen light bulb) is preferred and is transmitted along an optical fibre to the skin where multiple scattering occurs as photons interact with cellular and subcellular particles. Light can be absorbed by the haemoglobin present in the blood flowing in the tissue below the sensor before being scattered back along receiving optical fibres. The scattered light can be transmitted along a plurality eg in the preferred embodiment 6 separate fibres to 6 photodetectors via narrow-band optical filters all in the range 500 to 600nm (green/yellow visible light) and especially between 526 and 586. Generally, the number of detectors should be the same as the number of transmitting fibres. The sensor may optionally be heated above normal body temperature, to eg 40°C and up to 42°C for short periods the temperature may even reach 44°C. Alternatively, a single fibre of from 50 to 150nm in diameter may be used with one to three white LEDs.

According to a further feature of the invention we provide a "hand held" sensor device as hereinbefore described.

In particular, in the "hand held" sensor of the invention the optical fibre transmitting cable(s) may be replaced by a light emitting diode (LED) which significantly reduces the complexity of the sensor.

Before use, the sensor is normalised against darkness and a standard white surface, and the signal from each photodiode is measured to obtain the overall dark and "white balance" figures. Signal processing includes averaging for a period between 10 milliseconds to 10 seconds, subtracting the white balance signal, and taking a logarithm to produce a transmittance at each wavelength.

In the preferred embodiments, the use of 6 wavelengths gives the technique a considerable advantage over the pulse oximetry method which uses the minimum number of wavelengths necessary to obtain the information required. The use of more wavelengths in our method gives the technique stability against spurious disturbances at a particular wavelength, enables flexibility in the algorithm to cope with factors such as skin colour. Nevertheless, the sensor of the invention can utilise either oximetry or pulsed oximetry.

Averaging of the signal over a second or more also removes motion artefacts. It is also the case that the technique operates in the visible wavelength range. Thus, although the penetration of light into tissue is much less, the influence of poor contact with the tissue may also be considerably less thus reducing movement artefact. It is important to emphasis that our technique does not measure pulsatility as in the case in pulse oximetry.

SO_2 is the ratio of the oxyhaemoglobin (HbO_2) concentration to the total concentration of haemoglobin expressed as a percentage.

$$SO_2 = \frac{[HbO_2] \times 100}{[HbO_2] + [Hb]}$$

SaO_2 is arterial oxygen saturation

The reflected absorptions (A) at six wavelengths (500, 528, 550, 560, 572 and 586 nm) are used to calculate two parameters HbI and OXI:

$$HbI = (A_{528} - A_{520}) + (A_{550} - A_{528}) + (A_{572} - A_{550}) - (A_{586} - A_{572})$$

$$OXI = ((A_{550} - A_{50}O) + (A_{572} - A_{560})) / HbI$$

SO_2 is calculated from the formula:

$$SO_2 = 100 = (OXI - OXI_o) / (OXI_{100} - OXI_o)$$

Where OXI_o and OXI_{100} are empirically determined values for OXI at SO_2 values of 0% and 100% in skin.

The spectral range used for the algorithm is from 526 to 586nm and 22 absorption values are recorded within that range. The first process is to carry out a Kubelka and Monk transformation which reduces the intrinsic effect of the scattering of light within the skin.

The following operation is carried out:

$$\text{K-B Transformed spectrum} = 0.5 \times (R^2)/(1-R)$$

where R is the remitted spectrum (Reference: Kubelka, P and Munk F, Ein eitrag zur Optik der Farbanstriche, Zeitschrift fur technische Physik, 11a:593-601 (1931)).

In a paper presented by Wolfgang Dümmler in 1988, he describes that, according to the Kubelka-Munk theory (see Section II.2), the remission of an infinitely thick sample is dependent only on the quotients of absorption and scattering coefficients and is given by:

$$R_\infty = A/S + 1 - \sqrt{\{A/S\ (A/S + 2)\}}$$

The equation can be solved explicitly according to A/S

$$A/S = 0.5\ (R_\infty + 1/R_\infty) - 1$$

where R is the remitted spectrum that is the spectrum of light scattered back from the skin.

The transformed spectra are then "straightened" by subtracting the interpolated straight line joining the absorption values at the isosbestic wavelengths of 526 and 586nm. This, in part compensates for the melanin concentration.

The straightened spectra are normalised by division by the integral of the absorption values from 526 to 586nm.

The algorithm can make use of two reference spectra. These spectra may be from whole blood (measured in a cuvette) or spectra recorded in skin or the mean spectra recorded from several individuals. One reference spectrum is of fully oxygenated haemoglobin the other is of fully deoxygenated haemoglobin. The fully oxygenated spectrum is obtained by equilibration of whole blood in the cuvette with 95% oxygen and 5% CO_2 at 37°C or, in skin of the forefinger heated to 44°C at maximal reactive hyperaemia following release of the inflatable cuff after 6 minutes of brachial artery occlusion. The fully deoxygenated spectrum is obtained by equilibration of whole blood in the cuvette with 95%N_2 and 5% CO_2 at 37°C or, in skin of the forefinger heated to 44°C at the end of a 6 minute period of brachial artery occlusion prior to release of the inflatable cuff. The reference spectra are K-M transformed, "straightened" and normalised as described above.

An iterative process sequentially "mixes" the two references spectra in increments of 1% until the best least squares fit is achieved with the measured spectrum using all the absorption values at the 22 wavelengths. The iteration typically starts by adding 100 parts of the fully oxygenated spectrum to 0 parts of the fully deoxygenated spectrum, then 99 parts of the fully oxygenated spectrum to 1 part of the fully deoxygenated spectrum and so forth until the sum of the squares of the differences between the measured absorption values and those obtained by combining the

reference spectra reaches its minimum value. The resultant SO_2 value is the proportion of the oxygenated reference spectrum in the best fitted spectrum (eg 80 parts of the fully oxygenated spectrum with 20 parts of the fully deoxygenated spectrum would give an SO_2 value of 80%).

A maximum limit on the least squares value is stipulated such that noise or artefacts in the recorded spectra lead to the rejection of the SO_2 value.

A further important aspect of this invention is the fact that our technique measures arterial blood oxygen saturation. This is achieved in the following way: at normal skin temperature an optical measurement made on the skin of a patient would measure the oxygen saturation of a mixture of venous and arterial blood in the capillaries. In our technique we heat the skin below the sensor to below 40°C. The effect of this application of heat is to cause an increase in skin blood flow, sufficient to cause the oxygen saturation of the blood in the capillaries in the skin to equilibrate with the arterial blood supply. In this way the optical device will measure the equivalent of arterial blood oxygen saturation.

According to a further feature of the invention we provide a method of monitoring of SIDS in infants which comprises attaching a calibrated sensor as hereinbefore described to the skin of a patient and emitting white light, detecting and a measuring the scattered light.

The invention will now be described by way of example only and with reference to the accompanying drawings in which Figure 1 is a schematic representation of the optical measurement method of the invention;

Figures 2(a) and 2(b) are both graphs which illustrate how the SO_2 values are calculated;

Figure 3 is a "hand held" sensor according to the invention;

Figure 4 is a representation of the schematic layout of the optical system of the sensor of the invention;

Figure 5 is a representation of the hand held sensor of the invention in use; and

Figure 6a to d are graphs representing measured SO_2 values for different skin colours.

The measurement technique can best be understood by reference to Figures 2(a) and 2(b). Analysis of the data to obtain an index of haemoglobin concentration and arterial oxygen saturation (SaO_2) is carried out as follows: the gradients between 5 isobestic wavelengths (500, 520, 548, 575 and 586nm) are added to given an index which is related to the haemoglobin concentration. This index is used to normalise the measured tissue spectra. The oxygen saturation (SO_2) is calculated from the gradients between the absorption peaks for de-oxygenated haemoglobin (560nm) and the two adjacent isobestic wavelengths (548 and 575nm) of the normalised spectra.

The most important factor influencing the stability of the SaO_2 lies in our 6 wavelength analysis technique which incorporates the 5 isobestic wavelengths and the single oxygenated/deoxygenated peak. The two accompanying Figures illustrate how the HbI and SO_2 values are obtained from the spectra. HbI is the modulus of the slopes of the lines connecting the isobestic points as shown in the first Figure 2(a): it can be seen that any change in the general level of the signal, such as may occur due to small changes in the distance of the probe from the skin would not have any significant influence on this value. The absorption spectrum may shift up or down, but the modulus of the slope remains constant.

SO_2 values (Figure 2(b) are calculated from the modulus of the slopes of the extinction values between the neighbouring isobestic points and the deoxygenated peak, normalised to the HbI value. We thus obtain not only an SO_2 value but, on the way, we can also obtain a measure of relative haemoglobin concentration (HbI) from our measurements.

CLAIMS

1. A sensor device which comprises light source means for emitting a light beam, optionally of a plurality of at least three different wavelengths, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged to provide signals corresponding to the intensities of the respective wavelengths received by the photodetector means the arrangement being such that the signal levels corresponding to the different wavelengths bear a predetermined relationship with each other, and signal processing means for processing the actual output signals from the photodetectors to cancel out variations due to motion artefact and to provide an output representing a parameter to be measured or monitored and substantially unaffected by motion artefact.

2. A method of graphical representation or determination of arterial oxygen levels which involves the use of an algorithm;

$$\text{K-B Transformed spectrum} = 0.5 \times (R^2)/(1-R)$$

where R is the remitted spectrum,

which involves the steps of measuring the remitted spectrum from a light source measuring arterial blood flow.

FIGURE 1

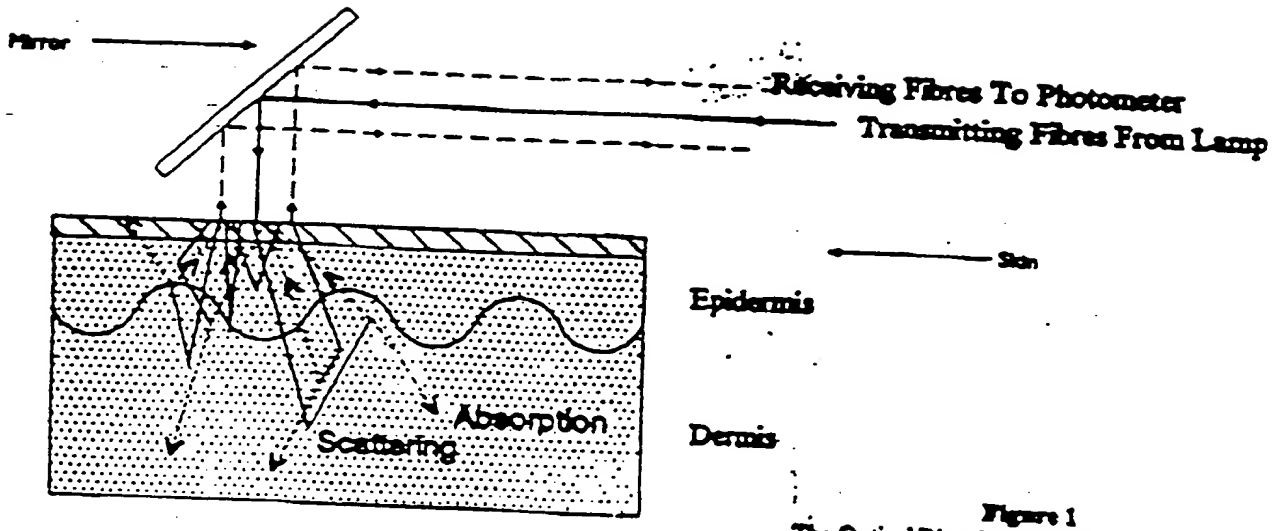

Figure 1
The Optical Blood Oxygen Saturation Sensor

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FIGURE 2

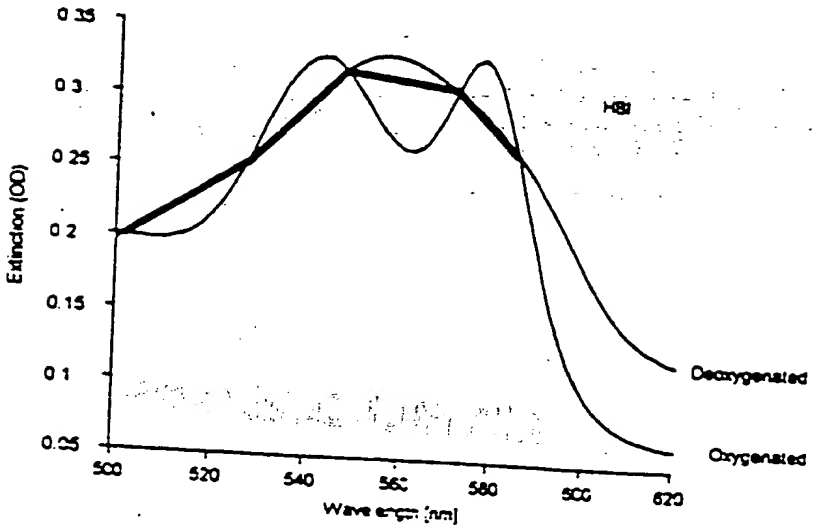

Figure 2(a)

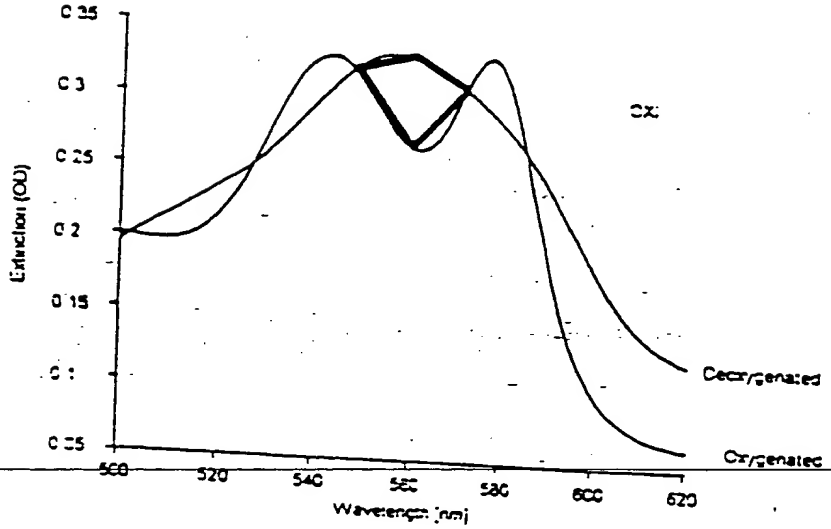

Figure 2(b)

FIGURE 3

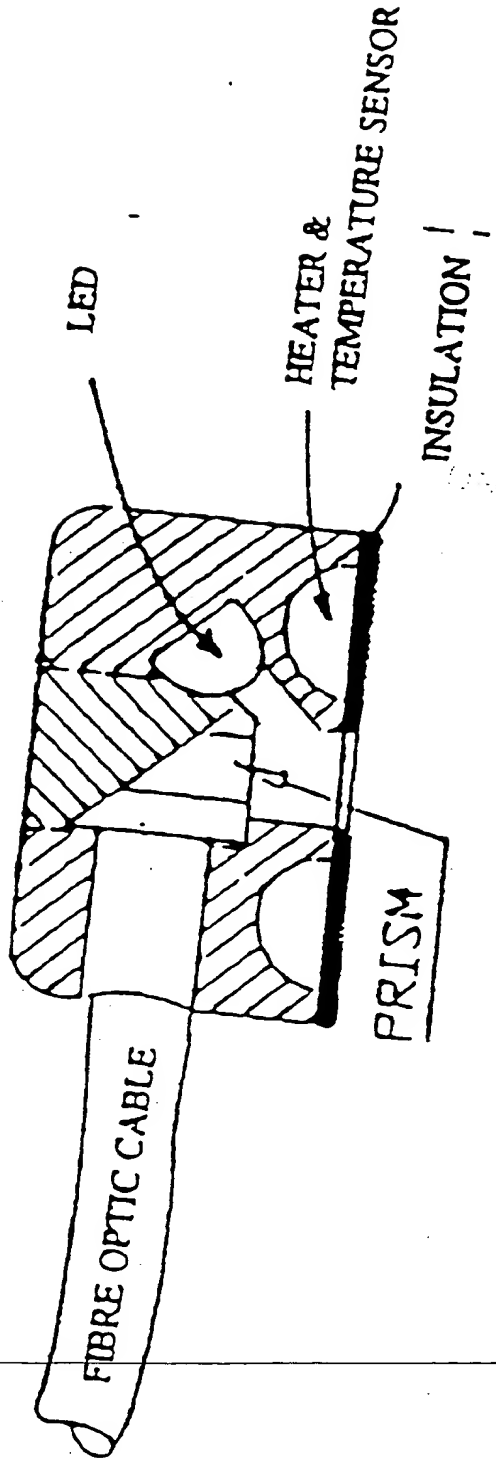
LED
HEATER & TEMPERATURE SENSOR
INSULATION
PRISM
FIBRE OPTIC CABLE

FIGURE 4

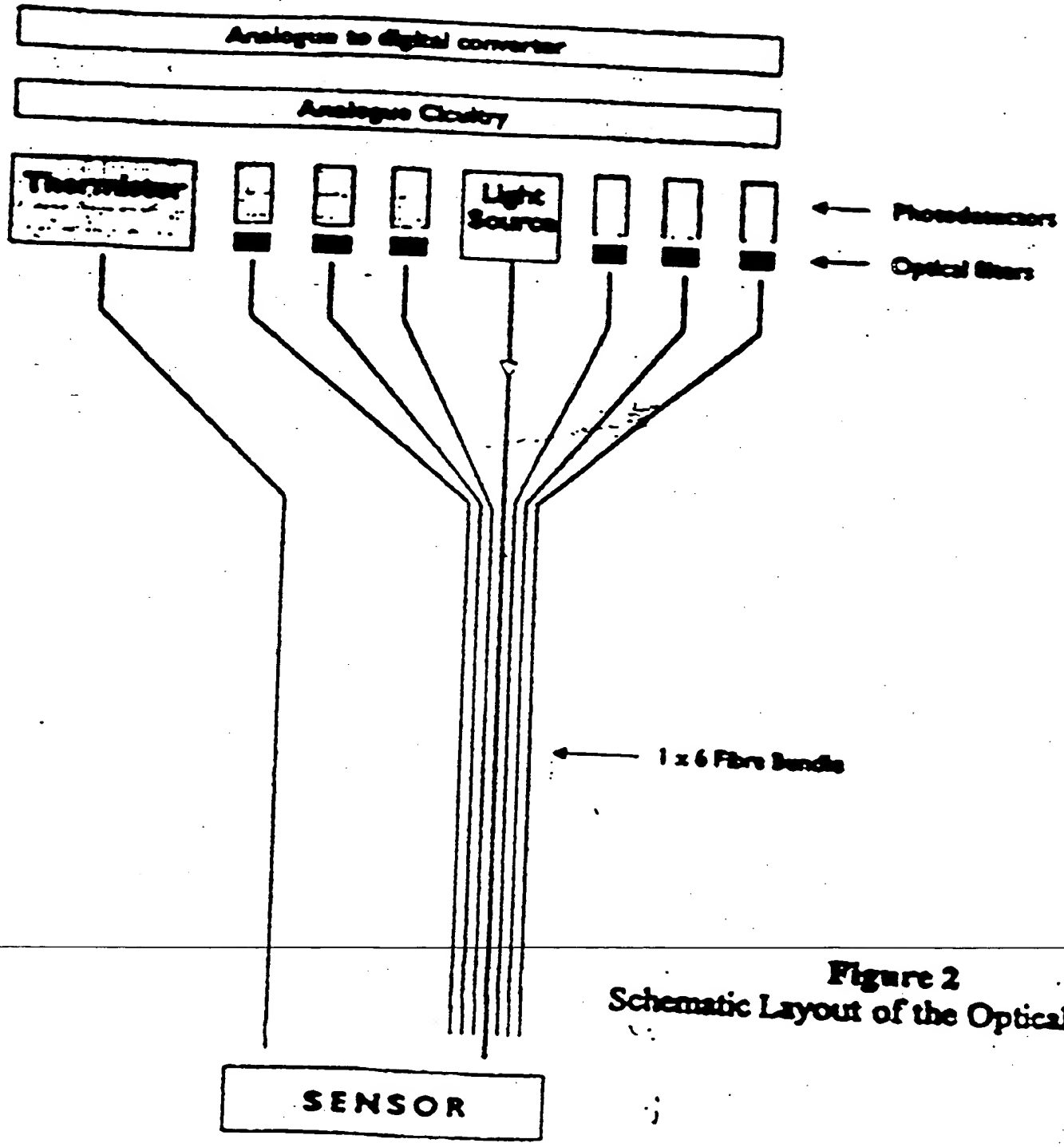

Figure 2
Schematic Layout of the Optical Syster.

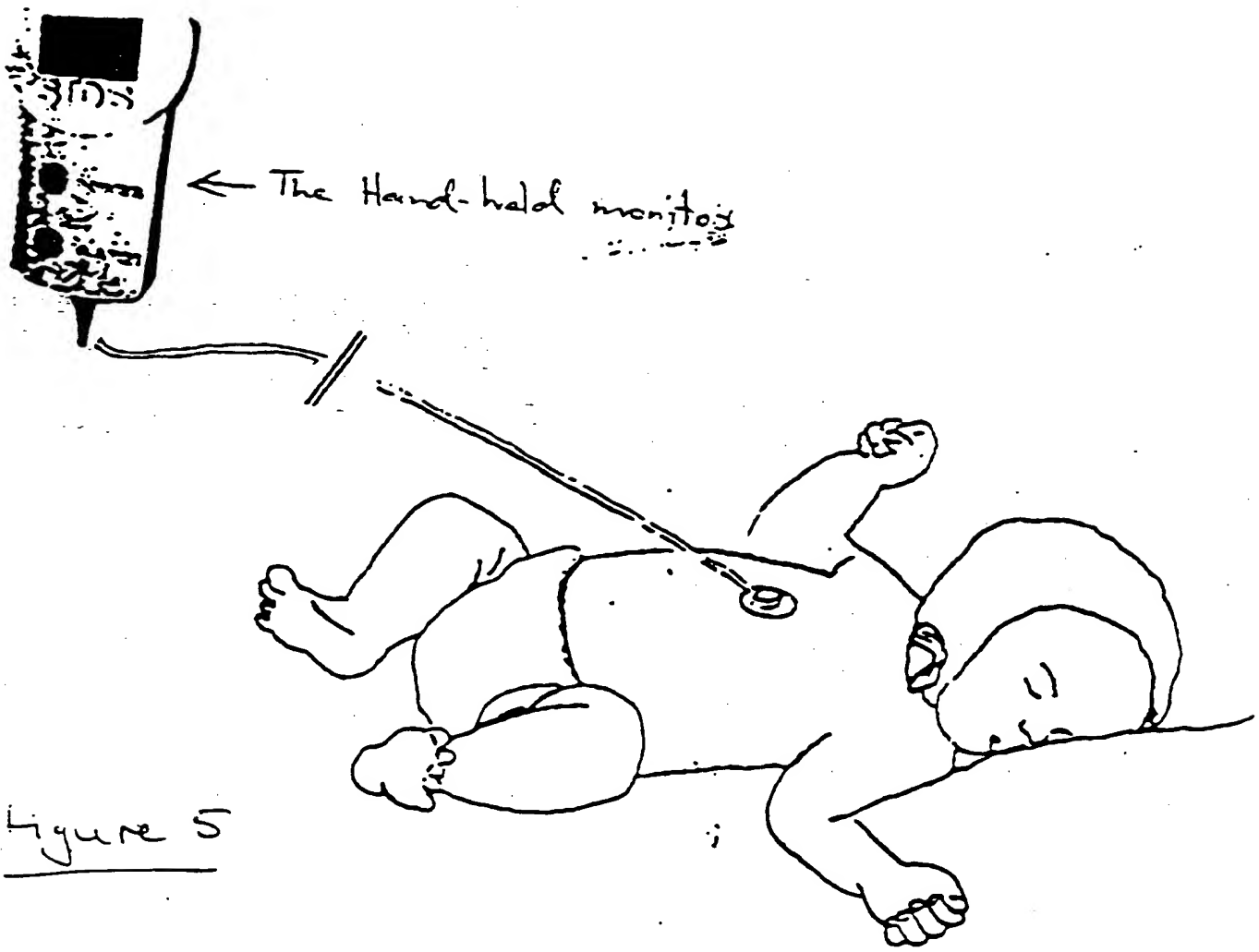

Figure 5

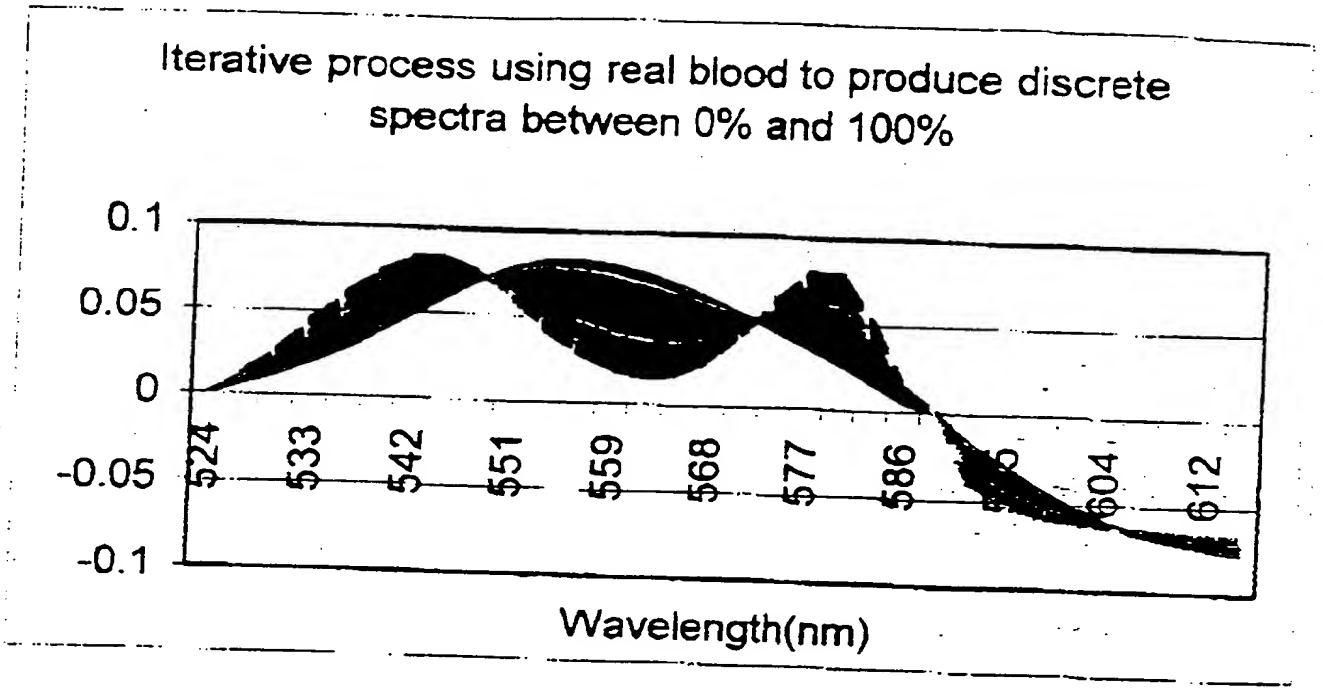

Figure 1

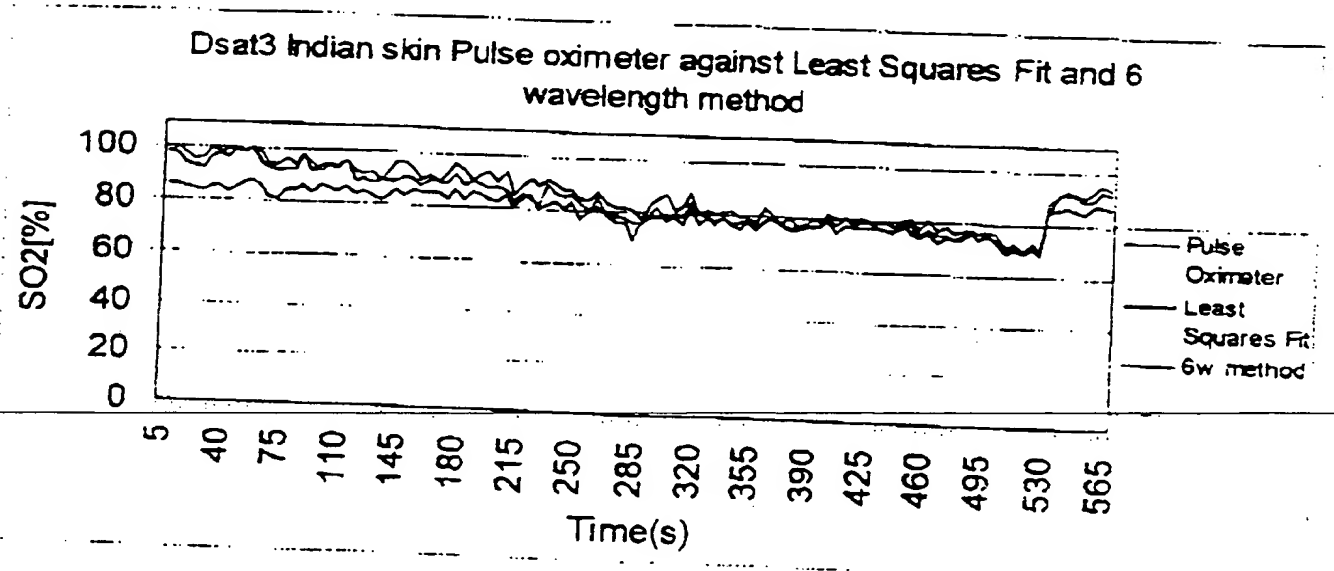

Figure 2

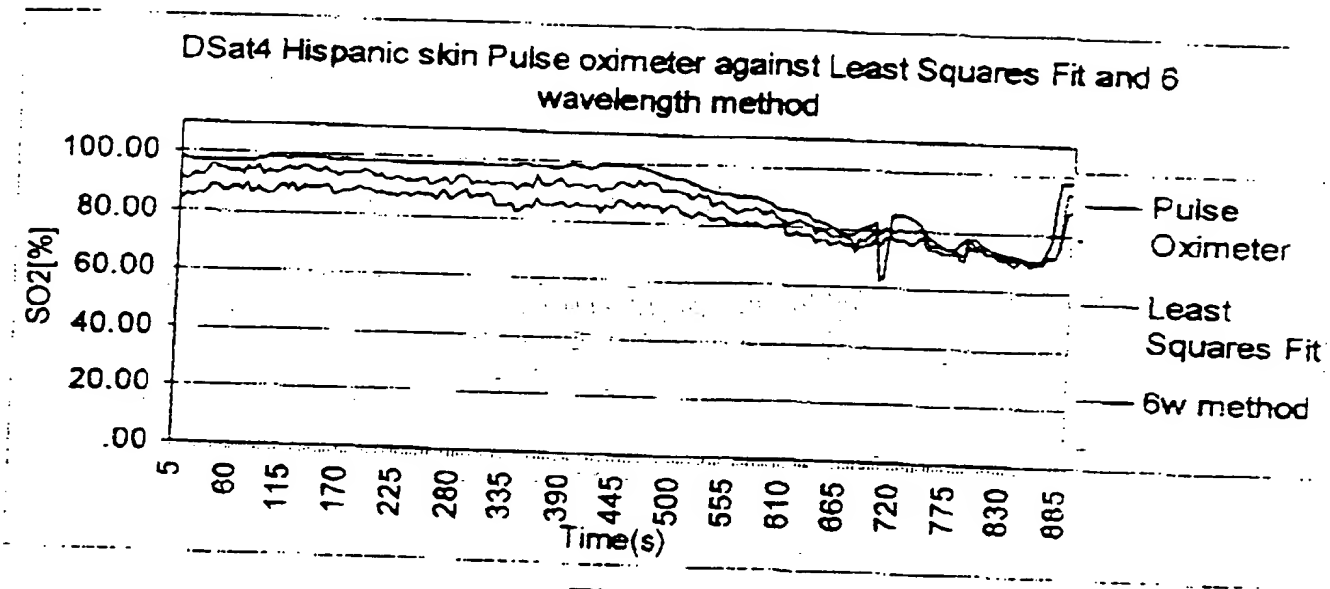

Figure 3

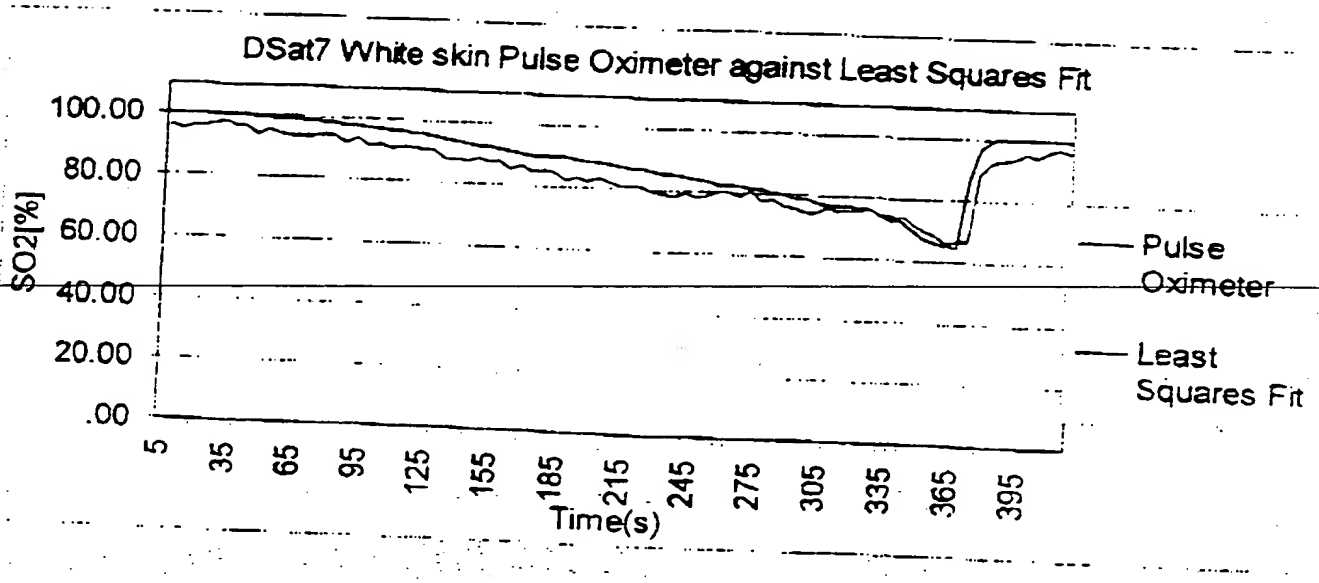

Figure 4

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Harrison Scotland Forte